DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 6, 2014

Altatec GmbH
C/O Ms. Linda K. Schulz, BSDH, RDH
PaxMed International, LLC
12264 El Camino Real, Suite 400
San Diego, CA 92130

Re: K133991
Trade/Device Name: iSy® Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: July 3, 2014
Received: July 7, 2014

Dear Ms. Schulz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K133991

Device Name: iSy® Implant System

iSy® Implant System implants are intended for immediate or delayed placement in the bone of the maxillary or mandibular arch. iSy® Implant System Abutments are intended for use as support for crowns, bridges or overdentures. When a one-stage surgical approach is applied, the implant may be immediately loaded when good primary stability is achieved and the functional load is appropriate.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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510(k) Summary

Altatec GmbH
iSy® Implant System
K133991

August 5, 2014

ADMINISTRATIVE INFORMATION

Manufacturer Name	Altatec GmbH Maybachstrasse 5 D-71299 Wimsheim, Germany Telephone: +49 7044 9445 0 Fax: +49 7044 9445 723
Official Contact	Tina Steffanie-Oak, Supervisor, Regulatory Operations
Representative/Consultant	Linda K. Schulz, BSDH, RDH Kevin A Thomas, PhD PaxMed International, LLC 12264 El Camino Real, Suite 400 San Diego, CA 92130 Telephone: +1 (858) 792-1235 Fax: +1 (858) 792-1236 Email: lschulz@paxmed.com kthomas@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	iSy® Implant System
Common Name	Endosseous dental implant
Classification Name	Implant, endosseous, root form Endosseous dental implant abutment
Classification Regulations	21 CFR 872.3640, Class II
Product Code	DZE, NHA
Classification Panel	Dental Products Panel
Reviewing Branch	Dental Devices Branch

INTENDED USE

iSy® Implant System implants are intended for immediate or delayed placement in the bone of the maxillary or mandibular arch. iSy® Implant System Abutments are intended for use as support for crowns, bridges or overdentures. When a one-stage surgical approach is applied, the implant may be immediately loaded when good primary stability is achieved and the functional load is appropriate.

DEVICE DESCRIPTION

The iSy® Implant System is an endosseous dental implant system designed for ease of use. Each product package contains the components needed for implant placement, impression taking, gingival contouring, and temporization. Components available with the iSy Implant System include the implant, implant base, cover cap, multifunctional cap, gingiva former, universal abutment and Titanium base CAD/CAM. The implants are provided in three diameters (3.8, 4.4 and 5.0 mm) and three lengths (9, 11, and 13 mm). The implant/abutment interface is identical for all sizes and, therefore, only one abutment connection is necessary. The implant base is a mount, supplied with the implant, that also can be used for temporary restoration. Titanium base CAD/CAM is an abutment designed to be used with the Sirona CAD/CAM System in Coris ZI meso L and meso S to fabricate a hybrid abutment with an angle up to 20°. The cover cap, multifunctional cap and gingiva former are temporary abutments used during healing. The universal abutment and titanium base CAD/CAM are abutments used for final restoration. The iSy implants are made of unalloyed titanium, iSy implant base, universal abutment and Titanium base CAD/CAM are made of titanium alloy, and iSy cover cap, multifunctional cap and gingiva former are made of polyetheretherketone.

EQUIVALENCE TO MARKETED DEVICE

Altatec GmbH submits the following information in this Premarket Notification to demonstrate that, for the purposes of FDA's regulation of medical devices, iSy® Implant System is substantially equivalent in indications and design principles to the following legally marketed predicate devices:

Altatec GmbH, CONELOG® Implant System cleared under K113779;

Altatec GmbH, CAMLOG Implant System Modified Implants and Abutments cleared under K083496;

Astra Tech AB, OsseoSpeed™ Plus cleared under K120414; and

Sirona Dental Systems GmbH, Sirona Dental CAD/CAM System cleared under K111421.

Non-clinical testing data submitted, referenced, or relied upon to demonstrate substantial equivalence included: engineering analysis, dimensional analysis, and static and dynamic compression-bending testing according to ISO 14801 *Dentistry – Implants – Dynamic fatigue test for endosseous dental implants.* Clinical data were not submitted in this premarket notification.

The subject device and the predicate devices encompass the same range of physical dimensions and characteristics, including implant diameter and length, and similar surface treatments. Any differences in the technological characteristics between the subject and predicate devices do not raise new issues of safety or efficacy.

	Subject Device	**Predicate Devices**			
	Altatec GmbH iSy® Implant System	Altatec GmbH CONELOG® Implant System K113779	Altatec GmbH CAMLOG Implant System Modified Implants and Abutments K083496	Astra Tech AB OsseoSpeed™ Plus K120414	Sirona Dental Systems GmbH Sirona Dental CAD/CAM System K111421
Design					
Implant Length, mm	9- 13	7.0- 16	9.0 - 16	6 - 17	NA
Implant Diameter, mm	3.8- 5.0	3.3- 5.0	3.3- 6.0	3.0 - 5.4	NA
Abutment Diameter, mm	6.5	3.3 - 5.0	3.3- 6.0	3.0 - 5.4	3.3 - 6.5
Abutment Angle	Straight, up to 20°	Straight, up to 30°	Straight up to 20°	Straight, up to 30°	Straight, up to 20°
Material					
Implant	CP Ti Gr 4	CP Ti Gr 4	CP Ti Gr 4	CP Ti Gr 4	NA
Abutments and Abutment Screw	Titanium Alloy; Zirconia	Titanium Alloy	Titanium Alloy; Zirconia	Titanium Alloy; Zirconia, Gold alloy, PEEK	Titanium Alloy; Zirconia
Implant Surface	GBE	GBE	GBE	GBE	NA

Overall, iSy® Implant System has the following similarities to the predicate devices:

- has the same intended use,
- uses the same operating principle,
- incorporates the same basic design,
- incorporates the same or very similar materials, and
- has similar packaging and is sterilized using the same materials and processes.

The data included in this submission demonstrates substantial equivalence to the predicate devices listed above.